

## **REMARKS**

The Rejection of November 28, 2005 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is respectfully requested. Applicants again thank the Examiner for his remarks and suggestion to provide a Declaration to underscore the teachings provided by the application under consideration. More specifically, Applicants thank the Examiner for his substantial efforts in guiding Applicants toward allowable subject matter. It should be noted that Mark A. Perreault, whose Declaration is filed herewith, is the expert working for Applicant in the TFF area. He has many years in the field and has worked with the inventors. A partial curriculum vitae is provided.

## **STATUS OF THE CLAIMS**

Claims 1-6 and 10-72 are currently pending in this application and are under examination. No claims have been amended herein. No claims are canceled herein. Consideration of the Declaration provide herewith is duly requested.

## **CLAIM REJECTIONS – 35 U.S.C. § 112, FIRST PARAGRAPH**

Submission of Claims 1-6 and 10-72 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Respectfully, Applicant has consistently taken the position that the teachings and enablement provided by the Specification are more than adequate to generate the current claims. However, it is apparent that the Examiner objects to the scope of the claims under 35 U.S.C. § 112, first paragraph as failing to provide an adequate written description of how to practice the invention with to operation range and pressure dependence. This is evident through the Examiner's statements in the November 28<sup>th</sup> Office Action (see pages 2-3).

In response to this contention it first must be pointed out that with respect to biological inventions, as with all other inventions brought before the Patent and Trademark Office, the

standard for enablement, as proclaimed in the first paragraph of 35 U.S.C. §112 is that, "[T]he specification shall contain a written description of the invention, and the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." In applying the above standard to the instant claims depends on the teachings found in the specification. That is, present in the written portion, the Abstract or elsewhere in the application as originally presented.

Respectfully, an applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); MPEP § 2163. That is, possession and enablement of an invention may be shown in a variety of ways including description of an actual reduction to practice, through drawings, data tables, graphs, or figures. Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" Enzo Biochem, 323 F.3d at 963-65.

Moreover, the issue of adequate enablement then reasonably extends even to whether one skilled in the art can apply the teachings gained from working examples present in the specification regarding the claimed subject matter, even if experimentation is needed. Though not the case with the current application, this extension of patentability would subsume any difficulties with the current application. The answer provided by the Federal Circuit on this point is that enablement is not precluded even if some experimentation is required. See, In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988); In re O'Farrell, 853 F.2d 894, 7 USPQ2 1673 (Fed. Cir. 1988). The only limiting factor is that this experimentation must not be "undue" and that the guidance provided by the Applicant must be "adequate." In re Vaeck, 947 F.2d 488, at 496 (Fed. Cir. 1991). Respectfully, this standard is more than fully met by the disclosure

provided by the Applicants, as delineated and explicated in the attached Declaration, and appropriately limited by the scope of the claims. Reconsideration is respectfully requested.

#### **CLAIM REJECTIONS – 35 U.S.C. § 102**

Claims 1-7, 9-10, 14-19, 20-54, 59-61 and 71 have been rejected under 35 U.S.C. 102(b) as being anticipated by van Reis et al., United States Patent 5,256,294. Respectfully, the Declaration attached hereto explicates not just the minor differences separating van Reis from the current claims but demonstrates why the two publications are very distinct and separate methodologies approaching TFF. This is sufficient to defeat any anticipation under section §102(b) argument relative to any of the van Reis disclosures. This has been Applicant's position but the amended claims, as explicated by the Declaration from Mr. Perreault, demonstrate this more completely. Reconsideration is respectfully requested.

#### **CLAIM REJECTIONS – 35 U.S.C. § 103**

Claims 12-13 have been rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis et al., United States Patent 5,256,294 in view of Kuni Hau et al. Respectfully, the Declaration attached hereto explicates not just the minor differences separating van Reis from the current claims but demonstrates why they are very distinct and separate methodologies approaching TFF. This has been Applicant's position but the amended claims, as explicated by the Declaration from Mr. Perreault, demonstrate this more completely with regard to any obviousness rejection based on USC §103. Reconsideration is respectfully requested.

The Commissioner is authorized to charge any fee which may now or hereafter be due in connection with this Reply to GTC Biotherapeutics' Deposit Account No. 502092. Applicants also acknowledge that the application was withdrawn from issue and remains so, even though the issue fee has been paid.

Applicants respectfully submit that the pending claims of this application are in condition for allowance, and that this case is now in condition for allowance of all claims therein. Such

action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, the Examiner is invited to telephone the undersigned at the number given below.

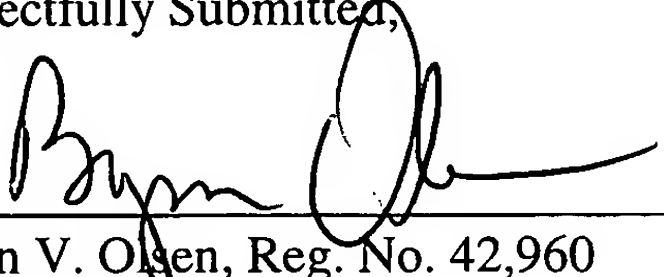
Early and favorable action is earnestly solicited.

Date:

12/14/2005

Respectfully Submitted,

By:



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